EQMS PROCEDURE 01

Organizational Context

How we determine internal and external issues, interested party requirements, the scope of our integrated management system, and the processes it contains.

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<Insert your organization name or logo>

Contents

Contents 3
1 Purpose 4
2 Scope 4
3 Requirements Addressed 4
4 Terms 4
5 Responsibilities 5
6 Triggers & Frequency 5
7 Method 6
7.1 Prepare the review 6
7.2 Analyze internal issues 6
7.3 Analyze external issues 7
7.4 Prioritize and act on issues 8
7.5 Determine interested parties and requirements 8
7.6 Determine the scope 9
7.7 Map and apply processes 10
8 Records 10
9 Performance Indicators 11
10 Related Documents 11

1 Purpose

This procedure sets out how we build and keep current a shared understanding of our context: the internal and external issues that shape our strategic direction and operational purpose, the interested parties that matter to our quality and environmental performance, and what those parties require of us.

The outputs of this procedure feed directly into Procedure 02 Risks & Opportunities, the EQMS policy, our objectives and the boundaries of the integrated management system. Context work is therefore the first link in our risk-based and opportunity-based planning, not a standalone exercise.

2 Scope

This procedure applies to all sites, functions and activities that fall within, or are being considered for inclusion in, the integrated management system. It covers:

- Identification, analysis and prioritization of internal and external issues, including environmental conditions and climate change.
- Identification of relevant interested parties and of their needs and expectations.
- Decisions on which interested party requirements we adopt and how they are addressed (including those that become compliance obligations).
- Determination and documentation of the management system scope, its boundaries and any requirement judged not applicable.
- Mapping of management system processes, their sequence and interaction, and the allocation of standard requirements to those processes.

Detailed assessment of the risks and opportunities that arise from context is carried out under Procedure 02 Risks & Opportunities. Legal requirements identified here are registered and evaluated under Procedure 04 Legal & Compliance Requirements.

3 Requirements Addressed

Standard	Clause(s)	What this procedure covers
ISO 9001:2026	4.1, 4.2, 4.3, 4.4	Context, climate change relevance, interested parties, scope, and QMS processes
ISO 14001:2026	4.1, 4.2, 4.3, 4.4	Context including environmental conditions, compliance obligations from interested parties, life cycle control and influence on the scope

4 Terms

Term	Meaning in this procedure
Context	The mix of internal and external issues that can influence how we set and achieve our objectives and the intended results of the management system.
Issue	A factor or condition, positive or negative, inside or outside the organization, that is relevant to our purpose and strategic direction.

Quadrant	Typical questions
Opportunities	Which trends could we exploit? Consider trained staff, certification, apprenticeships, new technology or markets, available premises and changing customer or social values.
Threats	What could harm us? Consider fines or regulatory action, tightening legislation, environmental incidents, aging assets, new competitors, staff shortages and the effects of climate change on our operations.

7.3 Analyze external issues

External issues are recorded on Form 01 and, where needed, explored using Form 03 PESTLE Analysis Template at local, regional, national and international level. Sources include market and competitor intelligence, supplier information, customer and product performance feedback, regulatory updates and lessons learned.

PESTLE prompts

Factor	Points to consider
Political	Trade policy, grants and funding, lobbying and pressure groups, conflict, government stability and change, shareholder demands.
Economic	Financial and economic trends, inflation, employment levels, emerging markets, supply availability and energy availability.
Social	Lifestyle and demographic trends, consumer behavior, environmental awareness, urbanization and demand for transparency.
Technological	Maturing and emerging technologies, automation, connectivity and digital data, new product and market possibilities.
Legal	Expected changes to law and regulation, outsourcing rules, administrative burden and legal constraints on our activities.
Environmental	Environmental conditions we affect or that can affect us: pollution levels, availability of natural resources, climate change, biodiversity and ecosystem health; also environmental regulation and investor expectations.

#	Action	Owner	Output/record
1	Determine whether climate change is a relevant issue for the quality management system and record the decision and its reasoning, whichever way it falls.	EQMS Manager	Climate change relevance statement on Form 01
2	For the environmental management system, record the environmental conditions being affected by, or capable of affecting, our operations.	Environmental Coordinator	Environmental condition entries on Form 01

> **2026 EDITION**
> ISO 9001:2026 requires us to determine whether climate change is a relevant issue. ISO 14001:2026 goes further: our issues must include environmental conditions such as pollution levels, resource availability, climate change, biodiversity and ecosystem health. A documented decision is expected in every case, including a decision that climate change is not relevant.

Handling strategy by Power score

Power score	Strategy	What we aim to do
1 to 3	Monitor	Watch for growing interest and any opportunity it creates.
4 to 6	Keep satisfied	Meet basic expectations, build interest, and watch for change.
7 to 11	Keep informed	Communicate regularly to maintain interest and detect change early.
12 to 16	Manage closely	Engage actively, secure ongoing support and review requirements frequently.

#	Action	Owner	Output/record
1	Submit the scored party list with proposed handling strategies for approval.	EQMS Manager	Approved Form 01
2	Decide for each requirement whether it is adopted into scope, customer requirements, operational controls or process controls, or escalated for risk assessment.	Top Management	Management Review Agenda & Minutes
3	Reassess parties when triggered: add new parties, re-rate requirements and compliance status, and adjust plans, schedules and budgets.	Department Managers	Updated Form 01
4	Monitor the effectiveness of the handling strategy and report changes in party needs and expectations as a management review input.	EQMS Manager	Management review input

7.6 Determine the scope

The EQMS Manager drafts the scope statement, taking account of the issues and requirements determined above, our products and services, our organizational units, functions and physical boundaries, and the planned or performed activities. For the environmental management system, the scope also reflects our authority and ability to control or influence the life cycle of our activities, products and services.

Boundaries and level of control

Boundary	What it covers	Authority to control or influence
Physical	Our premises at the addresses stated in the scope.	Full control of activities carried out on site.
Functional	All activities we perform and manage that result in product or service outputs.	High degree of authority over related processes.
Organizational	Processes performed by external providers to our specifications.	Controlled or influenced through purchasing and contract terms.
Life cycle	Upstream and downstream stages such as raw materials, transport, use, and end-of-life.	Influence through design, specification, supplier selection, and information to users.

The scope statement includes:

- The types of products and services covered and the sites and activities included.
- The applicability of ISO 9001 and ISO 14001 requirements, with justification for any ISO 9001 requirement judged not applicable and confirmation that this does not affect product or service conformity or customer satisfaction.
- Processes carried out by external providers and how they are controlled.